

REMARKS

Drawings

The drawings were objected to under 37 CFR 1.83(a) because it allegedly “fail to show the washer (140) as described in the specification.” *Office Action* at 2. As directed by the Office, a proposed drawing correction is submitted herewith. FIG. 1 has been amended to indicate a washer 140. The amendment has been made in red ink to clearly depict the proposed drawing correction. If the Office finds the proposed drawing correction acceptable, Applicants will submit a new formal FIG. 1 upon receipt of a Notice of Allowance.

Cancellation of Claims

Claims 10 and 29 are canceled herein without prejudice, waiver, or disclaimer. Applicants take this action merely to reduce the number of disputed issues and to facilitate early allowance and issuance of other claims in the present application. Applicants reserve the right to pursue the subject matter of those canceled claims in a continuing application, if Applicants so choose, and do not intend to dedicate any of the canceled subject matter to the public.

Response To Objections/Rejections

Response To Double Patenting Rejection

Claims 1-11 and 25-29 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 14 of copending Application No 10/602,981. Specifically, the Office states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/773,826 recite a system comprising a filter vessel, incubator, sample separation

system, image acquisition system, and robotic pipettor. The independent claim of 10/602,981 recites only the vessel and has dependent claims which recite an incubator, sample separation system, image acquisition system and robotic pipettor. It would have been obvious to one of ordinary skill in the art to combine each of the structures (vessel, incubator, separation system, image acquisition system and pipettor) into one system to allow samples to be processed more efficiently since the sample need only be introduced into one system, as opposed to being introduced into five different devices for processing. One system which allows all the processes to be carried out automatically reduces the need for user interference and thus increases the efficiency of the processes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Office Action at 6. Applicants respectfully traverse.

Nevertheless, to advance prosecution and facilitate early allowance of the claims, Applicants submit herewith a terminal disclaimer pursuant to 37 C.F.R. §1.321(c). Applicants have submitted the terminal disclaimer solely to advance prosecution of the application, without conceding that the double patenting rejection is properly based. In filing the terminal disclaimer, Applicants rely upon the rulings of the Federal Circuit that the filing of such a terminal disclaimer does not act as an admission, acquiescence or estoppel on the merits of the obviousness issue. See, *e.g.*, *Quad Environmental Tech v. Union Sanitary Dist.*, 946 F.2d 870, 874-875 (Fed. Cir. 1991); and *Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 941-942 (Fed. Cir. 1992).

Response To Claim Rejections Under 35 U.S.C. §102

Claims 1-6, 8, 11, and 25-27 have been rejected under 35 U.S.C. Section 102(b) as allegedly anticipated by *Yaremko et al.* Specifically, the Office Action states:

Yaremko et al teach an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500),

pipette assembly (400), washer (406, 410) and imaging system (606). The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, as recited in claims 1 and 25 (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filter is made of either beads or a porous gel material, as recited in claims 1, 3 and 4. The beads have a size of 10-100 microns, as recited in claim 5. *See* col. 6, lines 9-32. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 1, 8, 25 and 27 (col. 13, line 61 - col. 15, line 3). The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claims 1 and 25 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 1 (col. 13, lines 1-12). With respect to the washer recited in claim 2, Yaremko et al teach that washers (406, 410) contain liquids for rinsing or cleaning (col. 13, lines 23-2S).

Office Action at 3. Applicants respectfully traverse. For a proper rejection of a claim under 35 U.S.C. Section 102(b), the cited reference must disclose all elements/features of the claim. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 USPQ2d 1129 (Fed. Cir. 1988).

Yaremko et al. do not disclose, teach, or suggest all of the claimed elements. For example, *Yaremko et al.* disclose that their “[p]ipette assembly 400 also includes shallow and deep wash areas 406 and 410.... Wash areas 406 and 410 are wells or containers mounted on or recessed in instruments panel 106, and these wells or containers contain liquids for *rinsing or cleaning* pipette 402.” *Yaremko et al.* at col. 13, lines 24-29 (Emphasis added). Although *Yaremko et al.* describe “wash areas,” these are not the same as the washer recited in independent claims 1 and 25. According to the specification, the washer of claim 1 “is designed so as to wash all reagents from the antigen carriers present in the assay mixture, and through the filter 150 of the filter vessel 105.” *Application* at page 7, lines 9-11. Thus, the washer of claim 1 is not configured to *clean* the *pipettes* as disclosed by *Yaremko et al.*, but are rather designed to wash reagents from the assay mixture.

Nevertheless, to advance the prosecution and facilitate allowance of the claims, Applicants have amended claims 1 and 25 to include the features of their respective

dependent claims 10 and 29, *i.e.*, that the image acquisition system is a flow cytometer. Dependent claims 10 and 29 were not rejected based on allegedly being anticipated by *Yaremko et al.* Thus, incorporation of these features into independent claims 1 and 25 should obviate the rejection.

Thus, *Yaremko et al.* does not anticipate amended claims 1 and 25, and Applicants respectfully request that the rejection be withdrawn.

If independent claims 1 and 25 are allowable over the prior art of record, then their dependent claims 2-6, 8, 11, and 26-27 are also allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claims. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of claims 1 and 25, these dependent claims recite further features and/or combinations of features (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

Response To Claim Rejections Under 35 U.S.C. §103

(a) Claims 10 and 29 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Yaremko et al.* in view of *Layne et al.* Specifically, the Office Action states:

The disclosure of *Yaremko et al.* is described above. *Yaremko et al.* fail to teach a flow cytometer in the system for image acquisitioning.

Layne et al. is directed to an apparatus for automated testing of biological specimens *Layne et al.* teach that image acquisitioning in automated analyses allows detection of target individual cells and allows the collection of data to be observed by the user later. *Layne et al.* teach that flow cytometry is suitable for image acquisition (col. 14, lines 14-19; col. 17, lines 34-39). It would have been obvious to one of ordinary skill in the art to modify the *Yaremko et al.* reference by substituting the camera imaging system for a flow cytometry imaging system, as taught by *Layne et al.* In testing of blood specimens, such a modification would allow the user to detect and analyze individual blood cells.

Office Action at 4. Applicants respectfully traverse. It is well established at law that, for a proper rejection of a claim under 35 U.S.C. §103 as being obvious based upon a combination of references, the cited combination of references must disclose, teach, or suggest, either implicitly or explicitly, all elements/features/steps of the claim at issue. See, e.g., *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981).

The combination of *Yaremko et al.* with *Layne et al.* do not teach or suggest the features of claims 10 and 20. It should be noted that claims 10 and 29 have been cancelled; however, their subject matter, as noted previously, has been incorporated into their respective independent claims 1 and 25. Thus, Applicants now make their arguments with respect to the claimed subject matter of former claims 10 and 29 with respect to newly amended claims 1 and 25.

As noted previously, *Yaremko et al.* do not teach the washer of independent claims 1 and 25. *Layne et al.* do not cure this deficiency. Also, as admitted by the Office, *Yaremko et al.* failed to teach a flow cytometer as an imaging acquisition system. *Layne et al.* also do not cure this deficiency of *Yaremko et al.*

The only reference to a flow cytometer in *Yaremko et al.* occurs in the claims, *not* at col. 14, lines 14-19 as erroneously indicated by the Office Action. At column 14, lines 14-19, *Layne et al.* simply disclose that “the image acquisition and analysis SLM 224 detects individual HIV-infected cells within cell monolayers, and collects observable data. In one embodiment, the image acquisition and analysis SLM comprises a *digital image analysis system and motorized microscope stages*” *Layne et al.* at col. 14, lines 14-19 (Emphasis added). No where in the specification do *Layne et al.* teach that its digital image analysis system is in fact a flow cytometer.

Further, *Layne et al.* couple their digital image analysis system with motorized microscope stages. With respect to the claim language that includes a flow cytometer, the claim language reads as follows: “*multiple* detector instruments which are selected for the same biological specimen, in which are at least *two* of a digitized microscope, a colorimeter, a flow cytometer, and a scintillation detector.” *Layne et al.* at claims 12 and 23 (Emphasis added). Again, *Layne et al.* require, in addition to the flow cytometer, another type of detector instrument to analyze the biological specimen. The current

independent claims 1 and 25 use the flow cytometer system alone in the image acquisition system, and do not require multiple detector instruments.

In addition to this difference, the use of a flow cytometer as recited in claims 1 and 25 is not taught or suggested by the prior art. Flow cytometers are automated instruments that traditionally have been used to quantitate properties of *single cells, one cell at a time*. In contrast, claim 1 recites the following: “wherein the image acquisition system is a flow cytometer and is designed to detect the presence of interactions between the components and reagents of the assay mixture, *wherein said interactions are evidenced by agglutinations*.” *Claim 1*, as amended (Emphasis added). Thus, the flow cytometer as recited in the invention of claim 1 does not necessarily require single cells, but rather is being used to detect agglutinations of cells.

Independent claim 25 has been amended 25 has been amended to recite “a flow cytometer that analyzes the components... to determine the presence of interactions between the sample and the reagent, *wherein said interactions are evidenced as aggregated components*.” *Claim 25*, as amended (Emphasis added). The flow cytometer as recited in claim 25 is used to analyzed aggregated components, rather than single cells. Nothing in the cited references teach or suggest these features.

Hence the combination of *Yaremko et al.* in view of *Layne et al.* does not render claims 1 and 25 obvious. Applicants respectfully request that the rejection be withdrawn.

(b) Claims 9 and 28 have been rejected under 35 U.S.C. Section 103(a) as purportedly being obvious over *Yaremko et al.* in view of *Franciskovich et al.* Specifically, the Office Action states:

The disclosure of *Yaremko et al.* is described above. *Yaremko et al.* fail to teach a vacuum system for separating the sample.

Franciskovich et al. teach an apparatus for separating samples into their constituents. The reference teaches that both centrifuges and vacuums provide good means for separating multiple samples into their base constituents simultaneously. See col. 2, lines 2-5-31. Thus, it would have been obvious to substitute the centrifuge assembly of *Yaremko et al.* with a vacuum assembly as disclosed by *Franciskovich et al.* to allow simultaneous separation of multiple samples and thus increase the sample processing time.

Office Action at 4-5. Applicants respectfully traverse on the grounds that *Yaremko et al.* in view of *Franciskovich et al.* do not teach or suggest all of the features of independent claims 1 and 25. Nevertheless, this rejection has been rendered moot because dependent claims 10 and 29 have been incorporated into independent claims 1 and 25. Because independent claims 1 and 25 are allowable, their dependent claims 9 and 28 should also be allowable.

(c) Claim 7 has been rejected under 35 U.S.C. Section 103(a) as purportedly being obvious over *Yaremko et al.* in view of *Datar*. Specifically, the Office Action states:

The disclosure of *Yaremko et al.* is described above. *Yaremko et al.* fail to teach the particular filter materials recited in claim 7.


Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, *Datar* teaches separation devices such as bead columns. Further, *Datar* teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of *Yaremko et al.* These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Office Action at 5. Applicants respectfully traverse on the grounds that *Yaremko et al.* in view of *Datar* do not teach or suggest all of the features of claim 7. Nevertheless, to advance prosecution, claim 1 has been amended to incorporate the features of claim 10. Thus, because claim 7 depends from allowable claim 1, claim 7 should also be allowable. Applicants respectfully requests that the rejection be withdrawn.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1-9 and 11-29 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,

A handwritten signature in cursive script that reads "Cynthia J. Lee".

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